

SC SIVEL

Bastide Notre-Dame
Avenue Constantine
06160 Antibes FRANCE

tél 04 93 61 45 49 06 74 57 86 52
e-mail sc.sivel@wanadoo.fr

**Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room I-23
Rockville, MD 20857**

July 26, 2004

RE: Sterility Requirements for Inhalation Solution Products

To whom it may concern:

Some years ago new rule which would amend current regulations to require that all inhalation solutions for nebulization be sterile was proposed.

We agree with the assessment and recommendations proposed in the new rule. However, our concern is with the continued use of the current packaging, which for the concentrated dosage forms is bottles with droppers. As stated in the proposed rule, there is a high risk of contamination of inhalation solutions and the microbial contaminants are ubiquitous in nature. It goes on to correctly state that antimicrobial preservatives may not be effective due to resistance of the bacteria. Once the new rule is adopted and all inhalation solutions are required to be manufactured sterile and, assuming the same packaging and preservatives are used, it seems that the same potential for contamination problems would continue to exist when the dropper bottle is opened and used in a nonsterile environment.

Our company is developing a new pharmaceutical package that addresses the above referenced problems. This new packaging will allow product to be filled under sterile conditions or terminally sterilized and dispensed via a nonpressurized metered pump while maintaining absolute sterility throughout the use of the container.

The device comprises the following components:

- Rigid container for holding the product
- Manual airless pump mounted on the container for dispensing product in unit doses
- Filter for sterilizing outside air entering the container when the pump is actuated, located in an air intake passage in the base of the container
- One-way valve for preventing leakage of product through the air intake passage which is elastic and cooperates with a seat on or in a shaft integrated with the base

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This system makes it possible to package pharmaceutical products without any preservative and without any gas. and could find a very immediate application in saline diluter solutions or concentrate solutions for inhalation.

The patent for this device has been already delivered in the US (Patent 6,354,469 issued 12 March 2002).

We would appreciate any comments, suggestions or recommendations that you may have, and we would be very interested in knowing the way to have our packaging approved by your Administration.

Sincerely,



Jacques Pozzi